

REMARKS

These amendments and remarks are being filed in response to the final Office Action mailed November 15, 2007 (the "Office Action") and the Advisory Action mailed February 19, 2008. At the time of the Office Action, claims 12-23 were pending, with 15 and 20-22 withdrawn from consideration. The Office Action rejected all of the claims under 35 U.S.C. §103(a), non-statutory double patenting grounds, or both. The rejections and response thereto are set forth fully below.

By this Amendment, claims 17 & 20-22 are cancelled, claim 12 is amended, and claims 24-30 are added. No new matter is added.

Amendments to the Claims

By this Amendment claim 12 is amended and claims 24-30 are added. The amendment to claim 12 and new claims 24-28 and 30 are drawn to specific vitamins and supplements in specific amounts. Support for these amendments can be found throughout the specification including paragraphs [0017]-[0020].

New claim 29 is drawn to a cosmetic composition that includes any of a number of liquids. Support for this claim can be found throughout the specification, including paragraph [0032]. No new matter is added.

Claim Rejections for Provisional Obviousness-Type Double Patenting

In the Office Action, a provisional obviousness-type double patenting rejection was maintained against claims 12, 13 (in part), 14, 16-19 and 23 based on the combination of U.S. Applications 11/757,089 and 11/757,128 in view of Konikoff. Applicants indicated that these application numbers were accidentally created and that they were not active.

A review of PAIR for U.S. Application No. 11/757,128 demonstrates that on September 19, 2007, the status of this application was changed to "misassigned application number" and the transaction history indicates: "duplicate case has been deactivated." Accordingly, Applicants respectfully request that the provisional obviousness-type double patenting rejection based on U.S. Application 11/757,128 be withdrawn.

Similarly, on February 12, 2008, the status of U.S. Application No. 11/757,089 was changed to "Abandoned -- Incomplete Application (Pre-examination)" and the transaction history indicates: "Abandonment -- During Preexam Processing." Accordingly, Applicants respectfully request that the provisional obviousness-type double patenting rejection based on U.S. Application 11/757,089 be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 12, 13 (in part), 14, 16-19 and 23 were rejected under 35 U.S.C. § 103, as being unpatentable over U.S. Patent No. 5,122,418 issued to Nakane *et al.* (hereinafter "Nakane") in view of U.S. Patent No. 4,142,521 issued to Konikoff (hereinafter "Konikoff").

The claimed composition addresses the problem of producing a cosmetic composition that improves the absorption of vitamins and supplements (e.g. creatine) through the skin. Prior art approaches addressing this problem sought to utilize mixtures of vitamins and minerals with compounds known to improve skin absorption, such as surfactants and phospholipids. Such compounds are themselves capable of passing through the skin surface. Thus, unlike the prior art, the claimed composition provides improved skin absorption using particles that do not pass through the skin surface.

The skin is a structurally complex, relatively thick membrane that is designed to provide a barrier function. Molecules, such as vitamins and supplements, moving from the skin surface into and through intact skin must first penetrate the stratum corneum and any material on its surface. Such molecules must then penetrate the viable epidermis, the papillary dermis, and the capillary walls into the blood stream or lymph channels to be absorbed through the skin and into the organism. Molecules, such as vitamins and creatine, must overcome a different resistance to penetration in each type of tissue. For this reason, absorption of vitamins and supplements is substantially less than 100%. Transport through the skin membrane is thus a complex phenomenon. However, it is the cells of the stratum corneum, which present the primary barrier to absorption of topical compositions containing active agents, such as vitamins and creatine. In contrast, the skin barrier function is severely compromised when dealing with an open wound and healing is a different mechanism entirely.

With this background, Applicants wish to review the claimed invention as recited in amended claim 12.

12. (currently amended) A cosmetic composition containing an electret material which comprises

0.1 to 10% by weight of a cosmetically acceptable, solid electret material with a particle size of 0.05 to 100 μm , which electret material has an induced permanent dipole moment and a permanent electric dipole field with a field strength of 500 to 10^7 Vm^{-1} , the percentage data being relative to the total weight of the composition, and

furthermore comprising cosmetic carrier substances, cosmetic auxiliaries, further cosmetic active agents or a mixture thereof, and

a cosmetic active agent, selected from the group consisting of

a product containing Vitamin A that is added in an amount to impart at least 0.1% Vitamin A to the overall composition,

a product containing Vitamin E that is added in an amount to impart at least 0.1% Vitamin E to the overall composition,

a product containing Vitamin B that is added in an amount to impart 0.1 to 3 wt-% Vitamin B to the overall composition,

a product containing creatine that added in an amount to impart 0.1 to 3% creatine to the overall composition, or

a mixture thereof.

The claimed invention is drawn to a cosmetic composition that, when compared to a cosmetic composition that does not include the claimed electret materials, exhibits improved absorption of Vitamin A, Vitamin B, Vitamin E and Creatine through the skin, *see Specification, paragraph [0017]-[0019]*. The claimed cosmetics include 0.1 – 10 wt-% electret material and specified amounts of Vitamin A, Vitamin B, Vitamin E, creatine or a combination thereof. These specific amounts and ratios of ingredients cause skin absorption of the relevant vitamins and supplements to increase by at least 25%, *see Specification, paragraphs [0017]-[0019]*. This improved absorption of cosmetically active ingredients was a surprising result to the Applicants and was not disclosed or suggested by any of the cited references, whether alone or in combination.

The claimed compositions significantly improve skin absorption of an enumerated list of active agents, *see Specification, paragraph [0005]*. As described above, it was expected that improved absorption capacity could be achieved by utilizing a compound, such as a surfactant,

that can itself pass through the skin. In contrast to the expected solution, Applicants have discovered that improved absorption can be achieved using 0.05-100 μ m electret particles in very close contact with skin cells where each individual electret particle has a dipole moment of 500-10⁷ V/m, *see* Specification, paragraph [00018]-[00020].

While not wishing to be bound by theory, it is believed that the use of small particles causes dipole-dipole interactions between the dipoles of the individual electrets and the natural dipoles of the skin, such as cell membranes, proteins, peptides, amino acids, electrolytes, *etc.* The close contact between the skin and the individual electret particles, which enables these dipole-dipole interactions, is possible because of the dimensions of the particles and their direct contact with the skin. Prior to the filing of the instant application, this approach was not known to those of skill in the art.

Applicants reiterate that skin is a structurally complex, relatively thick membrane. Molecules, such as vitamins and creatine, moving from the environment into and through intact skin must first penetrate the stratum corneum and any material on its surface. Such molecules must then penetrate the viable epidermis, the papillary dermis, and the capillary walls into the blood stream or lymph channels to be absorbed through the skin and into the organism. Molecules, such as vitamins and creatine, must overcome a different resistance to penetration in each type of tissue. Transport through the skin membrane is thus a complex phenomenon. However, it is the cells of the stratum corneum, which present the primary barrier to absorption of topical compositions containing active agents, including vitamins and creatine.

Turning now to the Nakane reference. Nakane is drawn to a *composite powder* formed from a spherical core powder covered with a coating powder having an average particle size diameter that is one-fifth or less of the average particle size diameter of the spherical core powder, *see* Nakane, Abstract. The composite powder in Nakane can be used as part of a skin treatment agent, such as a sunburn preventing cosmetic and as a deodorant, *see id.*

Nakane was developed in order to capitalize on the benefits of the two powders while minimizing their drawbacks by combining them to form a composite powder, *see* Nakane, col. 4, ln. 64 - col. 5, ln. 9; col. 12, ln. 57 - col. 13, ln. 33. Nakane explains that many powders, for example hydroxyapatite, provide a significant benefit for skin care, but do not spread evenly over

the skin, *see* Nakane, col. 2, ln. 5-22. The powders that provide a significant skin benefit are not generally spherical. In contrast, spherical powders exhibit improved skin smoothness but are generally poor at hiding wrinkles when applied to the skin, *see* Nakane, col. 2, ln. 23-59.

Nakane attempts to leverage the advantages of both types of powders by forming a composite powder with a spherical core powder as a base that is covered with a significantly smaller diameter coating powder (such as hydroxyapatite), *see* Nakane, col. 4, ln. 64 – col. 5, ln. 9. The result is a generally spherical composite powder that exhibits the cosmetic properties of the coating powder, but spreads evenly like the spherical powders. Nakane discloses that the composite powder feels smooth and provides improved hiding power, *see* Nakane, col. 12, ln. 57 – col. 13, ln. 12.

Turning now to the Konikoff reference. Konikoff is drawn to a wound repair enhancement device in the form of a "self-contained, non-invasively applied bandage" that is light-weight and wafer-thin, *see* Konikoff, Abstract; col. 3, ln. 25-35. The wound repair enhancement device includes a thin film or foil of an electret material, which promotes healing of the skin, *see* Konikoff, Figures 1-3; col. 5, ln. 37-40 & 67-68; col. 6, ln. 4-5 & 14-17; col. 7, ln. 7-9 and 61-63. Konikoff teaches that the electret material is a polymeric film (3b & 13b) having vapor-deposited on one side thereof a layer of aluminum (3a & 13a), *see* Konikoff, col. 6, ln. 14-17 & Figures 1B & 2B. A ground strip (6, 16, or 26) is attached to the back side (3a & 13a) of the electret and the ground strip is placed in contact with the skin to "complete the circuit," *see* Konikoff, col. 7, ln. 4-39 & col. 7, ln. 54 – col. 8, ln. 2. In instances where exudates are present, the electret material is separated from the skin by a guaze (4) or sponge (14) structure, *see* Konikoff, col. 7, ln. 4-39. Presumably, this is because Konikoff teaches that electrets have been known to short out in the presence of a liquid, *see* Konikoff, col. 6, ln. 38-42.

Even where exudates are not present, Konikoff requires the use of a separate ground strip to complete the circuit, *see* Konokoff, col. 7, ln. 54 – col. 8, ln. 2. Thus, there is no disclosure or suggestion in Konikoff (i) that using an electret without a ground strip would be of any benefit to wound healing, or (ii) that using a polymeric electret that is not coated with a metallic foil would be of any benefit to wound healing.

The claimed cosmetic compositions include solid electret materials with a particle size of 0.05 to 100 μ m. The claimed cosmetic compositions are applied directly to the skin. In contrast to the usage of electrets disclosed in Konikoff, the claimed cosmetic compositions place electret materials in direct contact with the skin, where the electret materials do not include a ground strip or a metallic foil on one side of the electret. In addition, claim 29 specifically requires that the cosmetic composition include a liquid: "water, an alcohol, a polyol, an ester, a polar or non-polar oil, or a combination thereof." Thus, the Konikoff reference teaches away from the claimed cosmetic compositions.

Applicants note that amended claim 12 requires both 0.1-10 wt-% electret material and at least 0.1 wt-% Vitamin A, at least 0.1 wt-% Vitamin E, 0.1 to 3 wt-% Vitamin B, 0.1 to 3 wt-% Creatine, or a combination thereof. Nakane discloses over 100 individual other components that may be included in deoderant formulations, *see* Nakane, col. 11, ln. 18 – col. 12, ln. 25. Of the 100 named "other components," neither creatine nor any of the B Vitamins are mentioned by Nakane, *see* Nakane, col. 11, ln. 18 – col. 12, ln. 25.

Nakane discloses that the composite powder may be included in skin treatment agents, makeup type cosmetics, sunburn prevention cosmetics, and deoderants. Of these four embodiments, TEFLON® is only disclosed for use in sunburn preventing cosmetics, *see* Nakane, col. 10, ln. 19-29. Of the four embodiments, Vitamins A and E are only disclosed for use in deoderants, *see* Nakane, col. 11, ln. 69 – col. 12, ln. 1. The list of possible doederant components includes more than 100 specific materials and compounds, as well as fourteen references to general categories ("other oils and fats," "other waxes," etc.). Nakane also lists more than eighteen materials, including the broad polyester and epoxy categories, as options for the core resin powder, *see* Nakane, col. 10, ln. 23-33.

No mention is made of specific ranges of Nakane's "other ingredients;" however, two examples include one of the three claimed active ingredients. Examples 7 and 23 disclose a facial foundation and a sunburn preventing facial composition, respectively. Example 7 discloses a facial foundation containing 15 wt-% of a titanium oxide covered spherical cellulose composite powder and 0.05 wt-% vitamin E, *see* Nakane, col. 15, ln. 35 – col. 16, ln. 12. Example 23 discloses a sunburn prevention facial composition containing 20 wt-% of a zinc oxide covered

nylon composite powder and 0.05 wt-% vitamin E, see Nakane, col. 24, ln. 39-59. Even if the powder were TEFLO^N®, the amounts of both the powder and the vitamin E are outside the claimed ranges.

Even without considering the fact that Nakane does not disclose or suggest a TEFLO^N® electret, the vast number of specific materials and compounds and the large number of possible resin powders for the core creates at least 1800 possible combinations (this only considers the 100 "other ingredients" listed and the 18 specific core resin powders listed) from which a person of ordinary skill in the art must select in order to obtain the combination of TEFLO^N® and Vitamin E. *This does not even consider the claimed amounts of these ingredients, which raises the number of possible combinations exponentially.*

From this impossibly large number of options, the rejection requires the combination of (i) a resin, TEFLO^N®, that is only mentioned twice in the entire Nakane disclosure, (ii) a vitamin, vitamin E, that is only mentioned three times in the entire Nakane disclosure, (iii) where the only amount of vitamin E disclosed by Nakane is outside the claimed range, (iv) where the examples using vitamin E include a larger amount of a resin than that claimed, and (v) the examples using vitamin E use a resin different from that claimed. Even using this level of picking and choosing, the rejection still requires a person of ordinary skill in the art to modify the TEFLO^N®, for some unknown reason, in a manner that unexpectedly enhances absorption of vitamin A, vitamin E or creatine, through intact skin. However, there is no motivation to make such a modification because, prior to the filing of Applicants' application, it simply was not known that electrets could be used to enhance absorption of vitamin A, vitamin E, creatine, or any other supplement. Furthermore, Konikoff discloses that electrets benefit wound healing when used with a grounding strip that "completes the circuit." Clearly, the cited references do not provide motivation to make substitutions in a manner to produce the claimed cosmetic compositions or their unexpected results.

Even if each element of the claimed cosmetic was sufficiently described by the combination of Nakane and Konikoff, there would be no motivation to use a powder with the claimed electret properties. First, there was no known benefit of electret treatment of intact skin. Second, there is nothing to disclose or suggest that the amounts of powder and active agents could

improve absorption. Third, there is nothing to disclose or suggest that TEFLON® powder would improve absorption through intact skin. Finally, there is nothing to disclose or suggest that TEFLON®, combined with the claimed amounts of the specific active ingredients would lead to improved absorption through intact skin. Absent a recognition that the amounts of powder and active ingredients could impact absorption of the active agents through skin, these cannot be considered results-effective variables.

Even if Nakane did disclose the proper amounts of the claimed ingredients to achieve enhanced absorption of the claimed cosmetic active agents, there would be no motivation to combine the cited references to produce the claimed cosmetic compositions with electret TEFLON® particles. This is because the only reason Nakane provides for using TEFLON® particles is because they have a spherical shape and because Konikoff teaches the need for a ground strip and a metallic backing layer. Accordingly, both references teach away from cosmetic compositions having the claimed composition.

As noted in the Office Action, Nakane discloses that TEFLON, polytetrafluoroethylene (PTFE), may be used as the core powder, *see* Nakane, col. 10, ln. 23-30; col. 28, ln. 13-14. Nakane does not discuss any benefits of using TEFLON. However, Nakane clearly discloses that TEFLON is used as the core material, *i.e.* it is spherical. Thus, one of skill in the art would understand that TEFLON was selected because it is readily formed into the spherical form necessary for the core of Nakane's composite powders. As noted in the Office Action, Nakane does not disclose or suggest using TEFLON as an electret material.

Nakane is drawn to a composite powder that provides the benefits of both the spherical core powder and the coating powder. Nakane is not related to wound care. Konikoff's disclosure of TEFLON® electrets discloses a wound healing benefit, but no other benefits of a TEFLON® electret. In particular, there is no indication a TEFLON® electret provided any benefit to intact skin. As Nakane is not related to wound care, and adding an electret charge does not benefit the powder feel or hiding power, there would be no motivation to modify Nakane to include the electret TEFLON® disclosed in Konikoff.

As noted above, Nakane's reason for using PTFE is based nearly exclusively on the spherical morphology of small PTFE particles formed using emulsion polymerization. Because

shape is the relevant property, there is nothing in Nakane or elsewhere to motivate one skilled in the art to use an electret PTFE core in the composite powders disclosed therein. Similarly, Because Konikoff deals with wound healing, there is nothing in Konikoff's disclosure to motivate one skilled in the art to combine electret materials with active ingredients to provide *improved absorption of active ingredients*. In fact, Konikoff does not make any mention of vitamins, creams, lotions, medicines, medicants, or medications. Clearly, there is no motivation to combine the cited references to produce the claimed invention. Accordingly, Applicants respectfully request withdrawal of the current obviousness rejection.

Even if there were motivation to combine the cited references, there would be no expectation that the claimed combination would produce enhanced absorption of active ingredients. Although Konikoff discloses that it is known that small electric currents improve wound repair, it states that the reason for this "remains unclear," *see Konikoff, col. 1, ln. 21-24*. Because the mechanism that causes small electronic currents to improve wound healing is unknown, a person of skill in the art would not be able to predict whether small electronic currents would impact absorption of active ingredients or, for that matter, anything other than skin healing.

The improved absorption of the cosmetically active ingredients attributable to the presence of the electret material was completely unexpected and surprising to the inventors of the claimed invention. As noted above, there was nothing in the cited references that disclosed or suggested this interaction. This secondary indicia provides substantial evidence of nonobviousness.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to

be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,



Stephan A. Pendorf, Reg. No. 32,665
Gregory M. Lefkowitz, Reg. No. 56,216
AKERMAN SENTERFITT
222 Lakeview Avenue, Suite 400
West Palm Beach, Florida 33401-6183
Telephone: 561.653.5000

Date: March 17, 2008

Attorney Docket No.: 4034.003